Regulatory Affairs Course:-

Class Room: Training Fee & Duration : 20K & 3 Months	**Online** Training Fee & Duration : 23K & 3 Months

Introduction to different types of Pharmaceutical products:

- Drugs/Generics
- Biologics/Biosimilars
- Medical devices
- Radiopharmaceuticals
- Neutraceuticals
- Cosmetics
- Vaccines

Basic concepts on Rx, OTC, API, Starting material, DP/FP, Generics Vs Innovator drugs, Biologics VsBiosimilars, Laws Vs Regulations Vs guidelines.

Drug discovery and development

- Drug discovery stages and preclinical development
- Target identification, selection, validation, hit and lead identification, optimization, clinical candidate selection.
- Preclinical and clinical development
- Drug product approval process for new and generic drugs (US/EU/India)

Worldwide regulatory agencies and their role

- Key country agencies like India, US, Canada, EU, Australia and overview of their regulations
- Role of ICH, relevant ICH guidelines in QSEM and WHO in pharma industry (US/EU/India)

Approval process for each of the below products in US/EU/India: [covers development path, submissions, regulatory expectation for development, approval and market]

- Drugs (new and generic BA/BE)
- Biologics (new and biosimilars)
- Medical devices
- Combination products (drug-drug and drug-device) Vs FDC
- Orphan drugs

Post-market regulatory obligations

- Responsibilities and reporting of annual reports, post approval changes,
- Pharmacovigilance, post approval clinical studies and managing the outcomes.
- Advertising and labelling requirements

GLP's: 21 CFR 58 -The History of GLP, The Idea behind GLP, The Areas of Application, The Pillars of Good Laboratory Practice, Where Can GLP be Profitably Applied?, Indian GLP and International GLP.

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CMC topics: GMP (US/EU/Indian/ PIC), Pre-formulation studies (Drugs and Generics), ICH Q 7 guideline, 21 CFR 210 and 211, Medical device CE marking and ISO certifications.

Audits, pre and post approval Inspections, handling post inspection/ audit queries.

Collecting, organizing and compiling various regulatory submissions in compliance with the applicable regulations:

- IND/CTA/CTS
- NDA/MAA/NDS
- ANDA/505b2
- IMPD/DMF (types of DMF)/ASMF
- PMA and 510K
- CTD and e-CTD organization

ASEAN and BRIC regulations and registration process of Drugs and Biologics.

Different stages of interactions, briefing packages, responses and corrective measures during drug approval process with FDA.

PDUFA meetings and advisory committee meetings with US FDA, EU scientific advice.

Hands on workshops in next 15 days:

- Word template of CTD structure.
- Hands on work of filling different regulatory forms in US/EU/India.
- Preparing for Regulatory interviews (Example interview questions will be provided).

Communication skills:

- 2-3 seminars each of individual students to enhance their confidence and presentation skills.
- Explaining the real difficulties faced in a Pharma industry and providing Corrective and
- Preventive Actions (CAPA).

HR-Interview Etiquettes:-

- Communication Skill
- Office etiquettes
- E-mail etiquettes
- Presentation skills and Public speaking
- Interview preparation
- CV preparation
- Mock interviews
- Assessments

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